



Canadian Food
Inspection Agency

Agence canadienne
d'inspection des aliments

Undeclared Milk in Soy-Based Infant Formula – April 1, 2018 to March 31, 2019

Food allergen - Targeted surveys



Summary

Targeted surveys provide information on potential food hazards and enhance the Canadian Food Inspection Agency's (CFIA's) routine monitoring programs. These surveys provide evidence regarding the safety of the food supply, identify potential emerging hazards, and contribute new information and data to food categories where it may be limited or non-existent. We use them to focus surveillance on potential areas of higher risk. Surveys can also help identify trends and provide information about how industry complies with Canadian regulations.

Food allergies can affect people of all ages but are particularly common in children. Food allergens can represent a serious or life threatening health risk for allergic individuals. Allergens can be found in food due to their presence in the raw ingredients or they can be accidentally introduced along the food production chain due to cross contamination. Regardless of the source of the allergens, industry must ensure that the food produced is safe for human consumption, either by complying with specific Canadian regulations where applicable or by keeping the levels as low as reasonably possible.

The main objective of this survey was to obtain additional information regarding the presence and levels of undeclared milk in soy-based infant formula. 143 samples were tested, and none were found to contain undeclared milk.

Any positive results obtained during the course of these surveys would have been forwarded to the CFIA's Office of Food Safety and Recall (OFSR) to determine if the levels found would pose a health concern to allergic individuals. The extent of the follow-up actions taken by the agency is based on the seriousness of the contamination and the resulting health concern as determined by a health risk assessment. None of the products tested in this survey were positive for undeclared milk, and no health risks to consumers were identified.

What are targeted surveys

Targeted surveys are used by the CFIA to focus its surveillance activities on areas of higher health risk. The information gained from these surveys provides support for the allocation and prioritization of the agency's activities to areas of greater concern. Targeted surveys are a valuable tool for generating information on certain hazards in foods, identifying and characterizing new and emerging hazards, informing trend analysis, prompting and refining health risk assessments, highlighting potential contamination issues, as well as assessing and promoting compliance with Canadian regulations.

Food safety is a shared responsibility. The agency works with federal, provincial, territorial and municipal governments and provides regulatory oversight of the food industry to promote safe handling of foods throughout the food production chain. The food industry and retail sectors in Canada are responsible for the food they produce and sell, while individual consumers are responsible for the safe handling of the food they have in their possession.

Why did we conduct this survey

Approximately 7% of Canadians have self-reported as having at least 1 food allergy, but the actual number of medically confirmed food allergies is expected to be slightly lower¹. It is believed that the rate of food allergies is increasing, particularly among children. Food allergies are estimated to affect up to 5% of adults and up to 8% of children in developed countries². Food allergens are food proteins that can cause a reaction of the body's immune system, and can represent a serious or life threatening health risk for allergic individuals.

The priority food allergens are the 10 most common food allergens that are associated with severe allergic or allergy-like reactions in Canada. These allergens consist of peanuts, tree nuts, sesame, seafood (fish, shellfish and crustaceans), eggs, milk, soy, mustard, sulphites, and wheat³. This makes proper identification and labeling of allergens in food by the manufacturer essential.

Undeclared allergens can be found in foods due to their presence in the raw ingredients, or can be accidentally introduced along the food production chain through cross contamination. Regardless of the source of the allergens, industry must ensure that the food they produce is safe for human consumption. This can be achieved by complying with specific Canadian regulations where applicable, or by keeping the levels as low as reasonably possible.

This was the second survey conducted by the agency for undeclared milk in soy-based infant formula. The original survey was conducted in the 2013 to 2014 fiscal year. The main objective of this survey was to obtain additional information regarding the presence and levels of undeclared milk in soy-based infant formula.

All products were tested "as sold," meaning that they were not prepared as per the manufacturer's instructions or as they would typically be consumed.

What did we sample

All products were sampled between April 2018 and March 2019. Samples were collected from local and regional grocery stores located in 6 major cities across Canada. These cities encompassed 4 geographical areas: Atlantic (Halifax), Quebec (Montreal), Ontario (Toronto, Ottawa) and the West (Vancouver, Calgary). The number of samples collected from these cities was in proportion to the relative population of the respective areas.

The following products were **not** included in the survey:

- products with milk in the list of ingredients
- products with a precautionary statement for milk
- non pre-packaged products
- products with no list of ingredients
- products past the best before date

A total of 143 powdered infant formula were sampled, and they were all imported.

How were samples analyzed and assessed

Samples were analyzed by an ISO/IEC 17025 accredited food testing laboratory under contract with the Government of Canada. The samples were tested as sold, meaning that the product was tested as-is and not as prepared according to package instructions.

In Canada, food allergens and gluten must be declared in the list of ingredients if they are present in the prepackaged product in order to comply with the requirements of the [Food and Drug Regulations Section B.01.010.1](#). A prepackaged product will be deemed non-compliant if any level of undeclared allergens and gluten is detected.

What were the survey results

Of the 143 samples collected and tested in this survey, none tested positive for undeclared milk.

What do the survey results mean

Based on this survey, 100% of the products tested were compliant with allergen labelling regulations in Canada. No samples were shown to contain any detectable levels of undeclared milk.

The results from this survey are consistent with those found in a similar survey which was conducted in 2013 by the agency to obtain baseline information regarding the presence and levels of milk in soy-based infant formula⁴. In the 2013 survey, a total of 199 samples were tested, but only 88 samples were comparable to the products in the current survey. Of those 88 samples, none contained detectable levels of milk.

The extent of the follow-up actions taken by the CFIA is based on the level of contamination and the resulting health concern as determined by a health risk assessment. Appropriate follow-up actions include additional sample testing, facility inspection and product recall. The health risk

assessment is based on exposure to the allergens and gluten through consumption. The exposure is calculated by using the typical serving sizes for each food. Assessment based on serving size means not all detectable levels of undeclared allergens and gluten in food will cause a reaction in an allergic individual.

This survey generated additional information on the background level of undeclared milk in soy-based infant formula collected from 6 cities across Canada. Information gathered in this survey, in conjunction with other data including the Canadian Total Diet Study and Statistics Canada's Canadian Health Measures Survey food consumption data, are critical in assessing the health risk that our food supply poses to Canadian consumers. The results of the CFIA's surveillance activities are also used to inform the Canadian public and stakeholders by raising consumer awareness and help build public confidence in their food supply by removing non-compliant products.

References

1. Soller, L., Ben-Shoshan, M., Harrington, D. W., Fragapane, J., Joseph, L., Pierre, Y. S., Clarke, A. E. (2012). Overall prevalence of self-reported food allergy in Canada. *Journal of Allergy and Clinical Immunology*, 130(4), 986-988.
2. Sicherer, S. H., & Sampson, H. A. (2014). Food allergy: Epidemiology, pathogenesis, diagnosis, and treatment. *Journal of Allergy and Clinical Immunology*, 133(2), 291-307.e5.
3. [Common food allergens](#); (2018, May 14). Canada. Health Canada
4. [2013-2014 Undeclared Milk in Soy-Based Infant Formula](#); (2018, September 04). Canada. Canadian Food Inspection Agency.